OCT 2 3 2000

APPENDIX 7

K001163

510 (k) Summary
as required by 807.92 (c)
for DMLC IV - ERGO
Prepared 04/06/00

Submitted By:	3D line USA, Inc. 2807 Old Court Road Baltimore, Maryland 21208
Contact Person:	Karen H. Rigamonti, M.D. President
Device Trade Name:	**DMLC IV – ERGO**
Common Name:	Dynamic multileaf collimator and radiation therapy treatment planning system
Classification:	Radiation therapy beam shaping blocks were reviewed by the Radiology Panel and classified in Class II per 21 CFR 892.5710.
Predicate Device:	Multileaf Intensity Modulating Collimator (MIMiC) NOMOS Corporation 2593 Wexford Bayne Road Suite 315 Sewickley, PA 15143 K940412

Description of Device:

DMLC IV - ERGO is a combination of a radiation collimator with multiple tungsten leaves that move during delivery of radiation therapy and a computer based treatment planning and control system that both computes a radiation treatment plan and directs its implementation during delivery.

Intended Use of Device:

It is intended for use with rotating gantry linear accelerators to conform radiation dose delivery to geometrical volumes of specific shape containing pathology to be treated so that adjacent non-diseased tissues are spared to the extent possible.

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Substantial Equivalence to Predicate Device:

DMLC IV – ERGO has the same intended use, materials, and technological approach as the predicate device, **Multileaf Intensity Modulating Collimator (MIMiC)** (K940412) manufactured by NOMOS Corporation.

Clinically relevant characteristics of the devices are compared below.

Characteristics	DMLC IV-ERGO	NOMOS MIMiC
Indication **(Intended Use & Device Description)**	DMLC IV - ERGO is a combination of a radiation collimator with multiple tungsten leaves that move during delivery of radiation therapy and a computer based treatment planning and control system that both computes a radiation treatment plan and directs its implementation during delivery. It is intended for use with rotating gantry linear accelerators to conform radiation dose delivery to geometrical volumes of specific shape containing the pathology to be treated so that adjacent non-diseased tissues are spared to the extent possible.	NOMOS MIMiC - The intended use of the NOMOS Multileaf Intensity Modulated Collimator (MIMiC) is to provide 3-dimensional conformal treatments in external beam radiation therapy when used in conjunction with a medical linear accelerator. This is achieved by shaping the incident radiation field to the 2 dimension outline of the tumor margin utilizing the basic multileaf collimator design. Where necessary the beam intensity through the target volume can be modulated by moving the leaves of the MIMiC in and out of the radiation field to achieve the same effect as achieved in inserting a physical wedge or using the Varian Dynamic Wedge.
Leaf Characteristics	**Material:** Tungsten **Number:** 48 leaves double focused **Height:** 8 cm **Thickness:** <5 mm (isocenter) **Absorption:** less than 1.0% **Speed:** 1 cm/sec (at the isocenter) **Field Size:** 10 x12 cm approx. **Overtravel:** 2.5 cm approx.	**Material:** Tungsten **Number:** 40 leaves **Height:** 8 cm **Thickness:** 1 cm **Absorption:** Through leaf less than 1.0% Between leaves less than 1.0% **Speed:** Less than millisecond transition time to fully open or close
Treatment Modes	Allows delivery of dynamic shaping conformal therapy as a faster extension of the static shaping conformal radio therapy.	Allows delivery of the most conformal intensity modulated radiation therapy (IMRT) plan.
Controller Dimensions	20" x 20" x 15" Weight = 20 lbs.	13" x 9" x 5" Weight = 12 lbs.

Clinically relevant characteristics of the devices are compared below (cont.)

Interlock Box Dimensions	Inside the controller	7" x 5" x 3" Weight = 2 lbs.
Power Supply	100-240 V 50/60 Hz 400 Watt	**Power Supply Cable:** Rating: 300 V Connectors: 24 pin Lemo Length: Varies with accelerator **Air Cable:** Rating: 100 psi Connectors: multi tube with check valves Length: Varies with accelerator
Power Supply Dimensions	Inside the controller	17" x 14" x 7" Weight: 15 lbs.
Air Supply	No air supply is needed for the DMLC. The leaves are driven by DC motors.	**Voltage:** 115V / 60 HZ **Motor:** 0.55 HP (.40 KW) **Flow:** 1.25 cu.ft./min @ 120 psi **Power Consumption:** 440 Watts (5.4 amps) **Max Pressure:** 120 psi **Tank Size:** 4 gallons **Noise Level:** 45 dB (A) / 1 mtr **Dimensions:** 18" high x 15" diameter **Weight:** 65 lbs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2000

Karen H. Rigamonti, M.D.
President
3D Line USA, Inc.
2807 Old Court Road
Baltimore, MD 21208

Re: K001163
DMLC IV-ERGO
Dated: August 11, 2000
Received: August 11, 2000
Regulatory class: II
21 CFR 892.5710/Procode: 90 IXI
21 CFR 892.5050/Procode: 90 MUJ

Dear Dr. Rigamonti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

APPENDIX 1

Indication for Use Statement

510(K) Number (if known): K001163

Device Name: DMLC IV - ERGO

Indications for Use:

DMLC IV – ERGO is a combination of a radiation collimator with multiple tungsten leaves that move during delivery of radiation therapy and a computer based treatment planning and control system that both computes a radiation treatment plan and directs its implementation during delivery.

It is intended for use with rotating gantry linear accelerators to conform radiation dose delivery to geometrical volumes of specific shape containing the pathology to be treated so that adjacent non-diseased tissues are spared to the extent possible.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use___

(Optional Format 1-2-96

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) K001163